

K080504

3.0 510(k) Summary

Sponsor:

Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855
(906) 226-4812

MAR 20 2008

Contact: Jonathan M. Gilbert

Device Name:

LowTop Spinal Rod System

Classification Name:

LowTop Spinal Rod System components are Class III, as per the Code of Federal Regulations, Title 21, Section 888.3050, 888.3060 and 888.3070: Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System, and Pedicle Screw Spinal System. The product codes are NKB, KWP, KWQ, MNH, and MNI. The Panel code is 87.

Predicate Device:

K072187 – Pioneer LowTop Spinal Rod System (SE Date 10/12/07)
K070933 – Sanacor LowTop Pedicle Screw System (SE Date 6/13/07)
K070973 – Quantum Spinal System (SE Date July 3, 2007)
K070551 – Quantum Spinal System (SE date – March 29, 2007)
K041167 – Quantum Spinal System (SE date – July 23, 2004)

Intended Use:

The Pioneer LowTop Spinal Rod System components are non-cervical spinal fixation devices intended for use as an adjunct to fusion as a pedicle screw system (T1 - S2), a posterior hook and sacral/ilic screw fixation system or as an anterolateral fixation system (T8 – L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Material:

Materials used to manufacture the implants and instruments of this system are in conformance with ASTM Standard Specifications.

Performance Data:

Testing per recognized ASTM standards was presented.

Performance and SE Determination:

The LowTop Spinal Rod System implants are substantially equivalent to the components of a previously cleared Pioneer spinal system, with similar materials, performance, and indications for use demonstrated.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pioneer Surgical Technology
% Mr. Jonathan M. Gilbert
VP of Clinical & Regulatory Affairs
375 River Park Circle
Marquette, MI 49855

MAR 20 2008

Re: K080504
Trade/Device Name: LowTop Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, KWP, KWQ, MNH, MNI
Dated: February 22, 2008
Received: February 25, 2008

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K080504

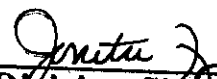
Device Name: Pioneer LowTop Spinal Rod System

Indications for Use: The Pioneer LowTop Spinal Rod System components are non-cervical spinal fixation devices intended for use as an adjunct to fusion as a pedicle screw system (T1 - S2), a posterior hook and sacral/iliac screw fixation system or as an anterolateral fixation system (T8 - L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
for Division of General, Restorative,
and Neurological Devices

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